

Remarks

This application has been carefully reviewed in light of the Office Action dated September 10, 2010. Claims 1-3, 5-16, 18-26, and 28-55 are currently in the application, with claims 1-3, 5-15, 29 and 36 having been withdrawn from consideration. Claims 41-55 have been added to the application. Claims 16 and 40 are the independent claims currently under consideration. Reconsideration and further examination are respectfully requested.

Claim Rejections - 35 U.S.C. § 102

Claims 16, 18-20, 23, 24, 26, 28, 31, 35, and 40 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,552,751 ("Inaba"). Applicant has reviewed the applied reference and respectfully submits that the claimed invention is patentably distinguishable over the applied reference for at least the following reasons.

Independent claim 16 is directed to a discrete film dosage to be taken orally, internally, or epidermally produced by the method including forming a non-gelatin polymeric film without active ingredients incorporated therein and applying a polar liquid carrier to one or more surfaces of the film, the polar liquid carrier incorporating at least one active ingredient. The method further includes allowing the applied polar liquid carrier to associate and cure with the film, to result in the complete absorption of the at least one active ingredient within the film forming a polymer film product.

As indicated above, the preamble of claim 16 has been amended to direct the claim to a discrete film dosage to be taken orally, internally, or epidermally. Support for this amendment may be found at least in the Abstract. Claim 16 also has been amended to specify that the non-gelatin polymeric film formed in step a) is without active ingredients incorporated therein. Support for this amendment may be found at least in originally filed claims 1 and 16 which

specified that the film may be formed with or without active ingredients. Claim 16 also has been amended to replace “liquid transport medium” with “polar liquid carrier.” Support for this amendment may be found at least in paragraphs [0058] and [0075] of the published application. Finally, claim 16 has been amended to specify that the applied polar liquid carrier associates and cures with the film to result in the complete absorption of the at least one active ingredient within the film. Support for this amendment may be found at least in Figures 2-4, together with the corresponding description in the specification. The other claims in the application were amended to be consistent with the amendments to claim 16. No new matter is believed to have been added to the application by way of these amendments.

Inaba is not seen to disclose the foregoing features of independent claim 16. In particular, Inaba is not seen to disclose or suggest at least the features of a film product made by applying a polar liquid carrier incorporating at least one active ingredient to one or more surfaces of a non-gelatin polymeric film and allowing the applied polar liquid carrier to associate and cure with the film to result in the complete absorption of the at least one active ingredient within the film.

As discussed in Applicant’s previous response, Inaba describes a multi-layered film preparation that includes at least two drug release controlling layers with at least one drug storing layer between the two drug release controlling layers. *See Inaba*, col. 2, lines 51-55. According to one process described in Inaba, a drug storing layer solution is coated on a film obtained from drying a drug release controlling layer solution and subsequently dried to prepare respective film-formed layers. *See Inaba*, col. 5, lines 18-24. The Office Action contends that the multi-layered film preparation described in Inaba anticipates the structure of the film produced by the steps recited in independent claim 16. Applicant respectfully disagrees.

Inaba is silent regarding the transport of the drug contained in the drug storing layers to the drug release controlling layers and the absorption therein. Even if a minimal amount of the drug contained in the drug storing layer of Inaba were to be absorbed by the drug release controlling layer, which Applicant does not concede, Inaba is not seen to disclose or suggest that the drug in the drug storing layer is completely absorbed by the drug release controlling layer. Arguably, Inaba teaches away from such an interaction between the layers in the multi-layered film preparation since allowing the drug to be transported from the drug storing layer and completely absorbed within the drug release controlling layer would defeat the respective purposes of these layers.

Therefore, independent claim 16 is believed to be allowable over Inaba. Reconsideration and withdrawal of the § 102(b) rejection of independent claim 16 are respectfully requested.

Independent claim 40 is directed to a non-gelatin polymeric film wherein the film includes two or more bands. At least one active ingredient is dispersed within a particular band. The film is a single film with structural homogeneity between the bands.

As discussed in Applicant's previous response, Inaba describes a multi-layered film preparation formed by either mounting prepared films on one another using a dry laminate or a wet laminate method, or coating a prepared film with a layer solution, which is subsequently dried to form a layer on the prepared film. The Office Action maintains that each layer of Inaba's multi-layered film is casted together to form a continuous structure. However, nothing in Inaba is seen to describe each layer in the multi-layered film as being cast together. Rather, as mentioned above, each layer used in Inaba's multi-layered film is seen to be cast individually. Furthermore, nothing in Inaba is seen to describe, nor has the Office Action cited any portion of

Inaba describing, the multi-layered film having structural homogeneity between the individually formed layers of the multi-layered film.

Therefore, independent claim 40 is believed to be allowable over Inaba. Reconsideration and withdrawal of the § 102(b) rejection of independent claim 40 are respectfully requested.

Claims 18-20, 23, 24, 26, 28, 31, and 35 are dependent from independent claim 16 described above and, therefore, are believed to be allowable over Inaba for at least the same reasons. Because each dependent claim is deemed to define an additional aspect of the invention, the individual consideration of each on its own merits is respectfully requested.

Claim Rejections - 35 U.S.C. § 103

Claims 25 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent Application Publication No. 2003/0183643 (“Fagen”). Claims 21, 22, and 37-39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent Application Publication No. 2004/0253434 (“Patel”). Claim 30 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of U.S. Patent No. 6,783,768 (“Brown”). Claims 33 and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Inaba in view of Fagen and further in view of U.S. Patent No. 7,112,361 (“Lynn”).

Claims 21, 22, 25, 30, 32-34, and 37-39 are dependent from independent claim 16 discussed above. None of the references applied in the § 103 rejections are seen to disclose or suggest anything to remedy the deficiencies of Inaba discussed above. Therefore, claims 21, 22, 25, 30, 32-34, and 37-39 are believed to be allowable over the applied references for at least the same reasons. Because each dependent claim is deemed to define an additional aspect of the invention, however, the individual consideration of each on its own merits is respectfully requested.

New Claims

New claims 41-55 have been added to the application. Support for the new claims may be found in the originally filed application and claims. For example, support for new claim 41 may be found at least in paragraph [0033] of the published application; support for new claim 42 may be found at least in originally filed claim 36; support for new claim 43 may be found at least in paragraph [0055] of the published application; support for new claim 44 may be found at least in paragraphs [0014], [0016], and [0055] of the published application; support for new claim 45 may be found at least in originally filed claim 3; support for new claim 46 may be found at least in originally filed claim 8; support for new claim 47 may be found at least in originally filed claim 9 and paragraph [0024] of the published application; support for new claim 48 may be found at least in paragraphs [0003] and [0027] of the published application; support for new claim 49 may be found at least in paragraph [0003] of the published application; support for new claim 50 may be found at least in paragraph [0003] of the published application; support for new claim 51 may be found at least in paragraph [0004] of the published application; support for new claim 52 may be found at least in originally filed claim 28; support for new claim 53 may be found at least in originally filed claim 28; support for new claim 54 may be found at least in originally filed claim 18 and paragraph [0038] of the published application; and support for new claim 55 may be found at least in paragraphs [0003] and [0027] of the published application. No new matter is believed to have been added to the application by way of these new claims.

Each of the new claims is dependent from independent claim 16 discussed above and, therefore, are believed to be allowable over the applied references for at least the same reasons. Because each dependent claim is deemed to define an additional aspect of the invention, however, the individual consideration of each on its own merits is respectfully requested.

Conclusion

The absence of a reply to a specific rejection, issue, or comment does not signify agreement with or concession of that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be other reasons for patentability of any or all claims that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment or cancellation of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment or cancellation.

In view of the foregoing remarks, the claims currently under consideration are believed to be in condition for allowance and such action is respectfully requested at the Examiner's earliest convenience.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502203 and please credit any excess fees to such deposit account.

Respectfully submitted,

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